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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

VENUS YAMASAKI, individually and on behalf of all others similarly situated,

Plaintiff,

v.

ZICAM LLC, and MATRIXX INITIATIVES, INC.,

Defendants.

CASE NO.: 3:21-cv-02596-HSG

PLAINTIFF'S OPPOSITION TO CHURCH & DWIGHT CO., INC.'S MOTION TO DISMISS

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Rules:

Plaintiff Venus Yamasaki ("Plaintiff") hereby responds in opposition to the Motion to Dismiss (ECF No. 37) filed by Church & Dwight Co., Inc., the successor to Defendants Zicam LLC and Matrixx Initiatives, Inc (collectively, "Defendants").[1]

I. PRELIMINARY STATEMENT

Plaintiff alleges that Defendants engaged in fraudulent, unfair, deceptive, and misleading advertising, marketing, and labeling in connection with the sale of Zicam® Original RapidMelts®, Zicam® ULTRA RapidMelts®, Zicam® Elderberry Citrus RapidMelts®, Zicam® Nasal Swabs, Zicam® Nasal Spray, Zicam® Wild Cherry Lozenges, and/or Zicam® Oral Mist™ (collectively, the "Zicam Products" or "Products"). Each of the Zicam Products is labeled as "Homeopathic," which is a 200-year-old pseudoscience that is not based on any accepted medical evidence supporting a product's purported safety or efficacy. ECF No. 30, First Amended Complaint ("FAC"), at ¶¶ 2, 21, 26-29. Despite the nebulous nature of homeopathic remedies, Defendants boldly and uniformly market and label their Products as being "CLINICALLY PROVEN TO SHORTEN COLDS." (the "Clinically Proven Claim"). As alleged, Defendants uniformly include the Clinically Proven Claim in a bold, all-capitalized font on the front and center of each Zicam Product label, and in their marketing and advertising materials, despite the fact that none of the Zicam Products are clinically proven to do anything, including shorten colds. FAC at ¶ 28.

Unlike over-the-counter ("OTC") drugs, the FDA does not evaluate or approve homeopathic products before they can be marketed or sold. FAC at ¶¶ 26-29. As a result, cunning profiteers can avoid regulation by labeling and marketing their products as "homeopathic." While there is no regulatory oversight for homeopathic products, such products are still subject to certain limitations – one of which is that, because homeopathic products are not scientifically proven to be safe and effective, they cannot be marketed or labeled as such. *Id.* Given the fact that all of the

[1] Pursuant to ECF No. 16, Defendants Zicam LLC and Matrixx Initiatives, Inc. certified that they merged into Church & Dwight Co., Inc., which filed the Motion to Dismiss.

Zicam Products are homeopathic, identically and deceptively labeled as "Clinically Proven to Shorten Colds," but are not clinically proven to shorten colds, they are substantially similar for purposes of Plaintiff's claims and are properly at issue in this litigation, regardless of whether each Product contains zinc as an ingredient.

Defendants' deception here is related to their uniform use of the Clinically Proven Claim on each Zicam Product at issue. This deception stems from the fact that (1) homeopathic products, by their very definition, cannot be clinically proven and the Zicam Products, in particular, cannot be clinically proven via Defendants' self-funded proprietary studies that have not been appropriately scrutinized by independent medical experts, and (2) the studies relied upon by Defendants regarding the efficacy of zinc, which they ascribe to both the zinc and zinc-free products on the Zicam website, actually show the *inefficacy* of zinc and in no way relate to Defendants' zinc-free products.

To be clear, Plaintiff is not suggesting that homeopathic remedies are unlawful or should not be sold. Rather, Plaintiff is simply arguing that Defendants are marketing the Zicam Products in a deceptive and unlawful manner. In other words, Plaintiff is arguing that Defendants take their label claims too far by promoting the Products as "Clinically Proven." As discussed herein, Defendants seek to have the definition and deceptive nature of their Clinically Proven Claim resolved through their motion to dismiss, but that is not ripe for resolution at this stage of the litigation.

1. The Zicam Homeopathic Products Are Not Scientifically Proven to Be Safe or Effective, and Thus Cannot Be "Clinically Proven to Shorten Colds."

By their very definition, homeopathic products cannot be clinically proven. In fact, as described below, the efficacy of homeopathic remedies has been repeatedly rejected by medical science. The U.S. Food and Drug Administration ("FDA"), the Federal Trade Commission ("FTC"), and the National Center for Complementary Integrative Health ("NCCIH"), a division

of the U.S. Department of Health and Human Services, have repeatedly and consistently stated that they are not aware of *any* scientific evidence to support the efficacy of *any* homeopathic products for *any* condition. Since the Zicam Products are homeopathic products, they are incapable of being clinically proven to do anything. But this has not deterred Defendants from boldly marketing the Clinically Proven Claim on the Zicam Products, which has misled reasonable consumers to believe that the Zicam Products have clinical proof as to their utility, when no such proof exists. There is no legitimate support for the Clinically Proven Claim, which is supposedly based on "internal," "proprietary," self-funded studies that have not been appropriately and scrutinized by the scientific community, and which cannot be attached to homeopathic products. ECF No. 37, Motion to Dismiss ("MTD"), at 1.

Unlike traditional medicines, the Zicam Products are not approved by the FDA, as there are no FDA-approved products labeled as "homeopathic." FAC at ¶ 26. Any product labeled as "homeopathic" in the United States has not been evaluated by the FDA for safety or effectiveness to diagnose, treat, cure, prevent, or mitigate any diseases or conditions. *Id.* at ¶ 29. Hidden at the bottom of their webpage, Defendants admit that the claims on the Zicam Products, including the "Clinically Proven Claim," are "based on traditional homeopathic practice, not accepted medical evidence, not FDA evaluated." *Id.* Defendants' veiled admission that the Zicam Products are not based on accepted medical evidence is inherently inconsistent with its bold, all-capitalized "Clinically Proven Claim" on the front and center of each Zicam Product, and is at the heart of Defendants' deception.

According to the NCCIH, "[t]here's little evidence to support homeopathy as an effective treatment for any specific health condition."[2] The NCCIH warns consumers: "Don't use

[2] www.nccih.nih.gov/health/homeopathy (last accessed August 6, 2021). "The mission of the [NCCIH] is to define, through rigorous scientific investigation, the usefulness and safety of complementary and integrative interventions and their roles in improving health and health care." *See* https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-center-complementary-

homeopathy to replace proven conventional care or postpone seeing a health care provider about a medical problem." Such warnings confirm that labeling a homeopathic product as "clinically proven" is highly problematic because it is intended to persuade consumers to believe that the product is a form of conventional care when it is not.

The FTC has expressed similar concerns, issuing a policy statement "in light of the burgeoning mainstream marketing of OTC homeopathic products alongside other OTC drugs," which confirmed that homeopathic theories are not accepted by most modern medical experts.[3] In its policy statement, the FTC states that, while the FTC Act requires OTC homeopathic products to be labeled as "homeopathic," "[t]he FTC Act does not exempt homeopathic products from the general requirement that objective product claims be truthful and substantiated." *Id.* For health, safety or efficacy claims, the FTC generally has required that advertisers possess "competent and reliable scientific evidence, defined as tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and [that] are generally accepted in the profession to yield accurate and reliable results." *Id* (emphasis added). In general, for health benefit claims, particularly claims that a product can treat or prevent a disease or symptoms, the substantiation required has been well-designed human clinical testing." *Id.* (emphasis added). Without question, the Clinically Proven Claim on the Zicam Products is a health benefit claim, and Defendants' admission that they did not publish their internal study confirms that the study cannot satisfy the requirements for establishing a Clinically Proven Claim. *See* Mot. at p. 10.

The FDA has also repeatedly confirmed that it is not aware of any scientific evidence supporting the efficacy of homeopathic products for any condition, whether a cold or otherwise. Because the FDA does not evaluate or approve homeopathic products before they can be marketed

integrative-health-nccih.

[3]www.ftc.gov/system/files/documents/federal_register_notices/2016/12/homeopathic_drugs_frn_12-13-2016.pdf (last accessed August 6, 2021).

or sold, companies, like Defendants, market their products as "homeopathic" to avoid FDA oversight. The FDA has detailed the dangers of homeopathic products, and affirmed that they cannot and should not be labeled as scientifically proven, in order to avoid consumer confusion:

> **What should consumers know about homeopathic products?**
>
> Products labeled as homeopathic and currently marketed in the U.S. have not been reviewed by the FDA for safety and effectiveness to diagnose, treat, cure, prevent or mitigate any diseases or conditions. FDA's evidence-based drug reviews play an essential role in ensuring that drugs are made with quality manufacturing processes, and are safe and effective for their intended uses. Products that have not been evaluated for safety and effectiveness may harm consumers who choose to treat serious diseases or conditions with such products, and consumers may be foregoing treatment with a medical product that has been scientifically proven to be safe and effective.[4]

Thus, the FTC, NCCIH, and FDA have all stated, in no uncertain terms, that homeopathic products are not supported by accepted medical evidence, as Defendants also surreptitiously admit, making the Clinically Proven Claim on the Zicam Products deceptive and misleading. Thus, this case is not an improper attack on substantiation because it is not possible for the Zicam Products to be "Clinically Proven."

Defendants contend that Plaintiff's logic is flawed because she did not locate any publicly available studies confirming that the Product labeling and marketing is false; however, it is Defendants' argument that is flawed. In addition to Defendants' inconspicuous website statement that the Zicam Products are not based on accepted medical evidence, which is a clear admission that the Products are not "Clinically Proven" (FAC at ¶ 29), Plaintiff's Amended Complaint cites multiple studies showing the Zicam Products are not clinically proven to shorten colds. Many of those studies were referenced by Defendants themselves in a footnote hidden at the bottom of their website, which did not include the actual studies, leading consumers to believe that those studies confirmed the clinical proof of the Products' efficacy. FAC at ¶¶ 6-12, 36-40. However, further

[4] www.fda.gov/drugs/information-drug-class/homeopathic-products (last accessed August 6, 2021).

research showed that those studies not only fail to support the Clinically Proven Claim, but prove it is false. *Id.* Significantly, Defendants' website cites the same clinical studies in support of the Clinically Proven Claim for their zinc products and zinc-free nasal spray products, which Plaintiff purchased. FAC at ¶ 11[5].

On the Zicam FAQ page, Defendants attempt to support the Clinically Proven Claim by citing to a study published in 2011 by the U.S. Cochrane Center ("Cochrane Review"), and to multiple studies and trials from the National Institute of Health ("NIH Review") FAC at ¶¶ 6-12. These studies unequivocally state that zinc products are *not* "Clinically Proven to Shorten Colds:"

- "While Zinc Gluconate reduced symptoms by one day in participants with experimental colds[6], zinc gluconate had no effect on symptom severity and zinc acetate had no effect on either duration or severity. Further, neither formulation had an effect on the duration or severity of natural cold symptoms. Evaluation of blinding, taste, and adverse events revealed no significant differences among the 4 treatment arms. Zinc compounds appear to have little utility for common-cold treatment." FAC at ¶ 10 (referencing NIH Review).

- "[w]e found no reason to recommend intranasal zinc gluconate or zinc orotate lozenges in treating common colds." *Id.*

- "…it is difficult to make firm recommendations about the dose, formulation and duration that should be used." FAC at ¶ 7 (referencing Cochrane Review).

- "…some caution is needed due to the heterogeneity of the data." *Id.*

Moreover, recent studies identified by Plaintiff indicate that use of OTC cold remedies containing zinc, including zinc acetate lozenges, do not shorten the duration of the common cold. *See* FAC at ¶ 37(citing https://bmjopen.bmj.com/ content/10/1/e031662 (last visited May 26,

[5] Defendants rely upon the same studies of zinc to support the Clinically Proven Claim on their zinc-free Zicam® Nasal Swabs and Nasal Spray products, which have not included zinc since Defendants recalled and reformulated the products in response to the FDA's 2009 warning letter, which was prompted by consumers losing their sense of smell due to zinc in the products. FAC at ¶ 11. It is unfathomable how a study regarding the efficacy of zinc can be relied upon to promote products that do not contain zinc. Thus, Defendants' reliance on zinc studies to support the Clinically Proven Claim on the zinc-free products is especially egregious and equally false.

[6] An experimental cold is a lab-induced cold and not a natural cold.

2021)). In 2019, a randomized, double-blind placebo-controlled trial conducted in Finland determined that "[t]here was no difference in the recovery rate between zinc and placebo participants during the 10-day follow-up." And while the "recovery rate for the two groups was similar during the 5-day intervention," for 2 days after the end of zinc and placebo use, "the zinc participants recovered significantly slower compared with the placebo participants…" The study concluded that "[a] commercially available zinc acetate lozenge was not effective in treating the common cold when instructed to be used for 5 days after the first symptoms." *Id.* Thus, along with Defendants' admission that the Clinically Proven Claim is not based on accepted medical evidence – as confirmed by the FDA, FTC and NICCH – the zinc studies Defendants seek to rely upon further confirm that the utility of zinc is nebulous and not clinically proven.

2. Defendants Went Too Far by Marketing and Labeling the Homeopathic Zicam Products as "Clinically Proven."

Defendants contend that "Zicam has proprietary clinical studies demonstrating that its cold remedy products, including Zicam Nasal Spray, shorten colds." MTD at 1. This directly contradicts Defendants' website admission that the Clinically Proven Claim on each of the Zicam Products is not based on accepted medical evidence. FAC at ¶ 29. Also troublesome is the slippery slope of Defendants' argument, which suggests that by simply placing "homeopathic" on the Product labels, they can forgo FDA oversight, inconspicuously admit on their website that the Product claims are not based on accepted medical evidence, yet still label the Products as "Clinically Proven," based on a self-funded, proprietary clinical study that they will never have to disclose to the public or subject to scrutiny by the scientific community.

Also troubling is Defendants' position in their reply in support of the Motion to Stay that "Clinically Proven" simply means that "a clinical study has shown that a product is effective for its advertised purpose." ECF No. 48, at 10. In other words, Defendants argue that the existence of and reliance on *any* clinical study, regardless of quality, type, or even the results of that study, is

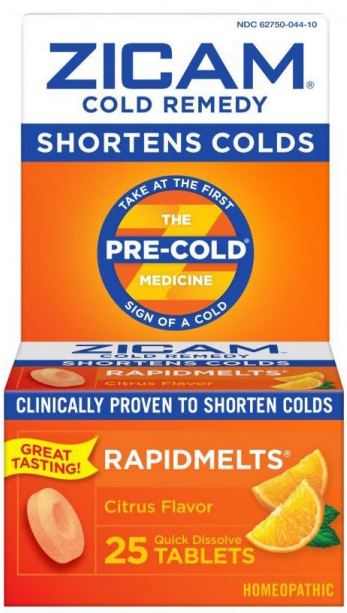
sufficient to support their Clinically Proven Claim. Therefore, according to Defendants, even a clinical study with less than ten participants, which is not randomized or double blind, and which is funded exclusively by Defendants, but which has been disputed by a dozen contrary studies, and which was conducted on animals and not humans, would allow Defendants to claim that the homeopathic Zicam Products are Clinically Proven to Shorten Colds.

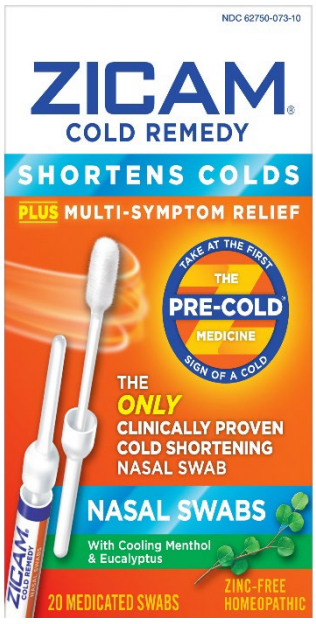
While Plaintiff passionately disagrees with Defendants' position, the viability of Defendants' position should not be tested at this stage of the litigation, but rather, following the parties' submissions of expert opinions. At this stage, Plaintiff's allegations confirm that homeopathic products cannot be clinically proven to do anything, including shorten colds. Plaintiff's allegations also include Defendants' own references to affirmative scientific evidence and scientific studies gathered from Plaintiff's independent investigation, which show that the Zicam Products are anything *but* clinically proven to shorten colds. Accordingly, Plaintiff's allegations are sufficient to survive dismissal.

Remarkably, in their reply in support of the Motion to Stay (ECF No. 48), Defendants also argue that no reasonable consumer would believe the Clinically Proven Claim means that the Zicam Products are *actually* clinically proven. *Id.* at 9-10. This defies logic and is inherently contradictory, but also begs the question why Defendants chose to use the Clinically Proven Claim on the Zicam Product labels. While premature for determination at this stage, the answer to this question is simple.

As addressed in detail in the Amended Complaint, Defendants have used the deceptive and misleading Clinically Proven Claim to achieve maximum profits at the expense of consumers. FAC at ¶ 13. The cold remedy market is highly profitable because there are always consumers seeking to relieve their cold symptoms so they can resume their daily activities without interrupting their work or personal schedules, particularly around cold and flu season. The cold remedy market is a highly competitive, multi-billion-dollar business, and companies like Defendants

distinguish themselves from the competition with captivating label and marketing claims. Zinc is one of the fastest growing segments of the vitamin, mineral, and supplement ("VMS") consumer market, and is an enormous profit center for Defendants, with Zicam's annual net sales projected at $90 million in 2021 alone.[7] As purveyors of VMS products in the United States, Defendants know that, when it comes to labeling and marketing, words matter. That is why Defendants chose to emblazon the front of every Zicam Product with the unambiguous representation, "Clinically Proven to Shorten Colds," in a bold, capitalized font, as seen below.



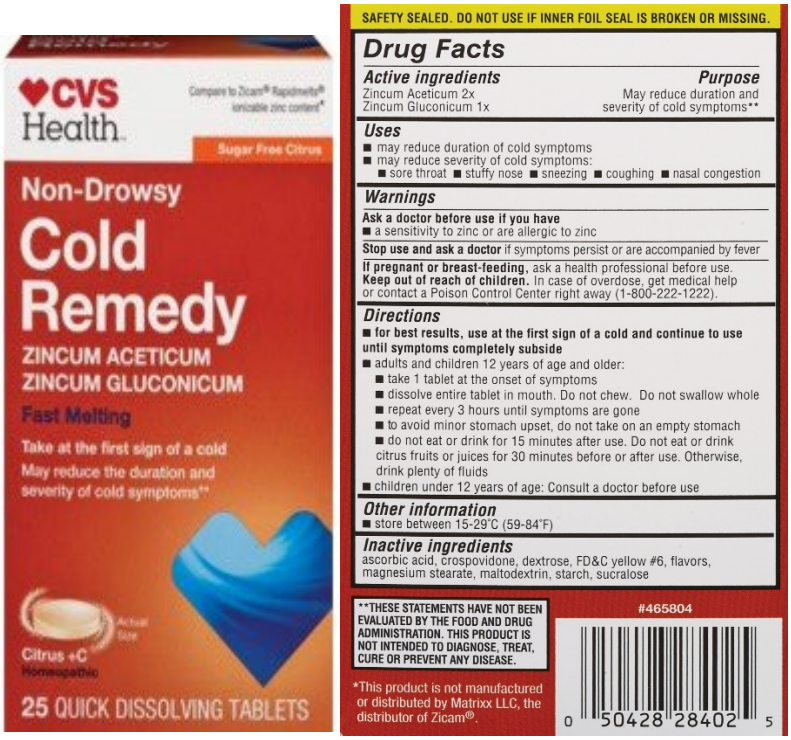


FAC at p. 10.

Defendants chose to label the Zicam Products in this way to impact consumer choices and gain market dominance, as they are well aware that all consumers who purchased the Zicam Products were exposed to, and would be impacted by, this misrepresentation, despite the fact that the Zicam Products are not clinically proven to shorten colds. Comparatively, competing homeopathic product labels simply state that the products "[m]ay reduce the duration and severity

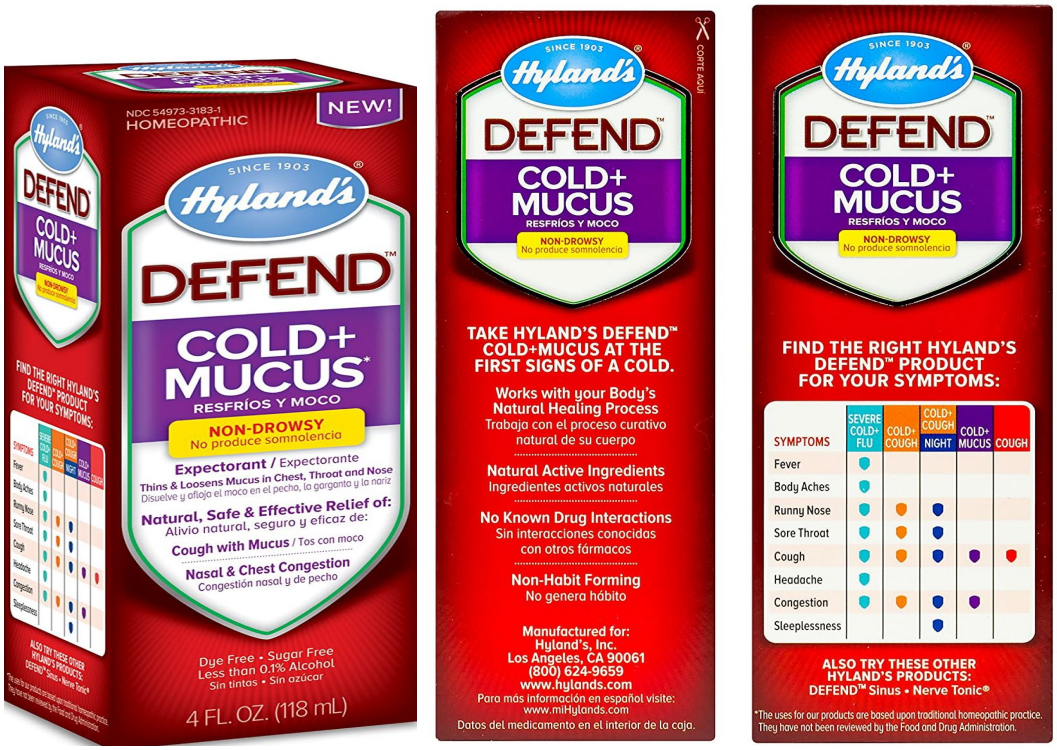
[7]https://www.businesswire.com/news/home/20201201005479/en/Church-Dwight-Acquires-Zicam-Brand-for-530-Million (last accessed August 3, 2021).

of cold symptoms,"[8] or that "the uses for our products are based on traditional homeopathic practice," and "works with your body's natural healing processes,"[9] as seen below.



[8] https://www.cvs.com/shop/cvs-health-cold-remedy-non-drowsy-quick-dissolving-tablets-25ct-lemon-lime-prodid-1011492 (last accessed August 9, 2021).

[9] https://www.amazon.com/Hylands-Homeopathic-Defend-Mucus-Fluid/dp/B00NNR2SOS/ref=sr_1_9?dchild=1&gclid=CjwKCAjwpMOIBhBAEiwAy5M6YB5rHGDvWI121U9NK538TphT0max8SMDNBXFpNQUV1XhBeQEavpe3RoCzvAQAvD_BwE&hvadid=177790750044&hvdev=c&hvlocphy=9012122&hvnetw=g&hvqmt=b&hvrand=15398844855864799 68&hvtargid=kwd-1540266072&hydadcr=21688_9710865&keywords=homeopathic+nasal+decongestant&qid=1628523919&sr=8-9



Unlike the Zicam Products, these competing products do not purport to be "Clinically Proven." This is because, for a claim to be considered scientifically and clinically proven, the claim must be widely accepted in its applicable field and have overwhelming evidence supporting it, including a consensus in the scientific community agreeing with the representations. Such consensus would require, at a minimum, sufficiently large, randomized, controlled, double-blind studies that have been scrutinized by peer review during the publication process and subjected to scholarly debate by diverse panels of scientific experts. Additionally, scientific consensus requires that published results be independently replicated by others using rigorous experimental design and data collection practices. If specific representations do not meet these standards, they cannot be considered scientifically and clinically proven, nor can they be considered to have reached scientific consensus. *See* FAC at ¶ 32 (stating that "Defendants' representations on their packaging and website convey to reasonable consumers – and reasonable consumers would believe – that the state of the science regarding the Zicam Products and their ingredients have reached a level of scientific consensus such that Defendants' claim that the Products are 'clinically proven to shorten

colds' is an established truth and statement of fact."); *see also e.g.,* Bauchner H, Golub RM, Fontanarosa PB. Reporting and Interpretation of Randomized Clinical Trials. JAMA. 2019; 322(8):732-735; Kirman CR, Simon TW, Hays SM. Science Peer Review for the 21st century: Assessing Scientific Consensus for Decision-making while Managing Conflict of Interests, Reviewer and Process Bias. Regul Toxicol Pharmacol. 2019; 103:73-85.

Thus, a manufacturer should not even consider using the phrase "Clinically Proven" on product packaging unless plainly supported by robustly designed, published, peer-reviewed clinical trials, which have been conducted upon the product being advertised or an identical formulation. There is no consensus in the scientific community that the Zicam Products are clinically proven to shorten colds, as no such evidence exists for homeopathic products in general or the Zicam Products in particular.

II. LEGAL STANDARD

"When evaluating a Rule 12(b)(6) motion, a court must accept all material allegations in the complaint—as well as any reasonable inferences to be drawn from them—as true and construe them in the light most favorable to the non-moving party." *Lytle v. Nutramax Labs, Inc.*, 2019 U.S. Dist. LEXIS 227970, at *3-4 (C.D. Cal. Dec. 6, 2019) **(**citing *Doe v. United States*, 419 F.3d 1058, 1062 (9th Cir. 2005)). To survive a motion to dismiss, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Lytle,* 2019 U.S. Dist. LEXIS 227970, at *5 (citing *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)). "The Ninth Circuit has clarified that (1) a complaint must "contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively," and (2) "the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Lytle,* 2019 U.S. Dist. LEXIS 227970, at *5 (citing *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011)).

III. ARGUMENT

1. Plaintiff's Claims Do Not Address the Zicam Products' Lack of Substantiation.

Defendants' lack of substantiation arguments, which address only Plaintiff's UCL and CLRA claims, entirely miss the mark. Plaintiff does not seek to rely upon a lack of substantiation claim, which "arises where, absent any evidence suggesting a representation is false or misleading, a plaintiff demands a defendant either 'put up or shut up.'" *Mier v. CVS Pharm., Inc*., No. 20-01979, 2021 U.S. Dist. LEXIS 76737, at *11-13 (C.D. Cal. Mar. 22, 2021) (quoting *Mullins v. Premier Nutrition Corp.*, 178 F.Supp.3d 867, 876 (N.D. Cal. 2016)). Here, for the reasons discussed above, there are no scientific studies that could support a Clinically Proven Claim for a homeopathic product, removing this case from the realm of a lack of substantiation defense. Further, Defendants have already "put up" the very studies they rely upon to support their Clinically Proven Claim and these studies confirm the falsity of the Claim.

At the outset, Defendants cite *Kwan v. SanMedica Int'l,* 854 F.3d 1088, 1091 (9th Cir. 2016) and misleadingly argue that the phrase "clinically proven" was at issue in that case. It was not. Rather, the plaintiff in *Kwan* alleged that the "clinically tested" representation at issue would lead consumers to believe the products were clinically proven, which the court rejected, indicating a distinction between the claim that a product is "clinically tested" versus "clinically proven." Further, in *Kwan*, the plaintiff admitted that the products were clinically tested, precluding her from arguing that the "clinically tested" claim was false.

The distinction between "clinically tested" and "clinically proven" was addressed by the court in *Lytle*, which rejected the defendant's lack of substantiation argument in an action challenging the defendant's clinically proven claims for a dog supplement. *Lytle,* 2019 U.S. Dist. LEXIS 227970, at *12-16. In *Lytle,* the plaintiff challenged defendants' representations that Cosequin dog supplements were safe, effective, and absorbable in peer-reviewed, published, controlled U.S. veterinary studies – in other words, that they were clinically proven. Relying upon

Kwan, the defendants sought to dismiss the plaintiff's allegations, which the court rejected, finding *Kwan* entirely distinguishable. *Id*. (citing *Kwan*, 854 F.3d at 1088). As the court found in *Lytle*, there is a marked difference between the "clinically tested" statement at issue in *Kwan* and "promises about the rigor of scientific testing or even positive findings…" *Lytle*, 2019 U.S. Dist. LEXIS 227970, at *13. The court also found that, "just like any other explicit statement made about a product, if a representation regarding the level of scientific support for a product is provably false, it is actionable." *Id.* at *15. Here, similar to *Lytle*, and unlike *Kwan*, Plaintiff "allege[s] that the specific kind of robust scientific support that Defendants represent exists does not, in fact, exist. If that allegation proves to be true, Defendants' statements are false—regardless of what other types of scientific support for the products exist." *Id.* Further, as in *Lytle*, Plaintiff here can carry her burden by establishing that the Zicam Products are not "Clinically Proven to Shorten Colds" by pointing, not only to the very studies Defendants seek to rely upon, but by identifying independent research that shows the Zicam Products do not have the level of scientific support necessary to support the "Clinically Proven" claim. It is not necessary to compel Defendants to substantiate their claims when they have already admitted on their website that the Clinically Proven Claim is not based on accepted medical evidence (which is confirmed by the FTC, NICCH and FDA), cited studies proving the Zicam Products are ineffective, and when Plaintiff has additionally cited independent studies establishing that the Zicam Products do not work, which Defendants fail to reference on their website. Thus, "Plaintiff's claim is not simply a lack of substantiation claim, but a claim that the Defendants' explicit statements regarding the scientific support for their [Zicam] products are false." *Id.* at *16.

Similarly, in *Nathan v. Vitamin Shoppe*, No. 3:17-cv-01590, 2019 U.S. Dist. LEXIS 41926, at *5-11 (C.D. Cal. Mar. 14, 2019), the court rejected the defendant's lack of substantiation argument in a case involving weight loss supplements promising "weight management" and appetite control," which led the plaintiffs to believe the product was an effective dietary aid that

would aid weight loss. To support their claims that the product advertising was false, the plaintiffs pointed to several studies showing that the products were not effective in aiding weight management as the product promised, which cast doubt on the product representations. The court thus found that the plaintiffs' claims were facially plausible because the plaintiffs pointed to evidence that directly conflicted with the advertising claims, and thus "the issue of whether the proffered studies do in fact show that [the Product's] representations are provably false is a question not properly decided on a motion to dismiss." *Id.* at *6-7, 11 (quoting *Vasic v. Patent Health, LLC*, 2014 U.S. Dist. LEXIS 33181, 2014 WL 940323, at *21-22 (S.D. Cal. Mar. 10, 2014) (rejecting lack of substantiation argument on motion to dismiss in action involving glucosamine supplements where plaintiff cited numerous studies showing the products did not have the health benefits represented, even though plaintiff did not test the products at issue, noting that "the crux of the disagreement between the parties focuse[d] on the strength of the evidence cited in the FAC," which should not be resolved on a motion to dismiss)).

Likewise, in *Liou v. Organifi, LLC,* 491 F. Supp. 3d 740, 750-751 (S.D. Cal. 2020), the defendant sought to dismiss the plaintiff's CLRA and UCL claims relating to Clinical Trial Statements on a juice product based on a lack of substantiation. Like the present matter, the defendant sought to rely upon numerous clinical trials published on a government website and supported by a prominent medical university, but neither of the links the defendant cited to, nor the results on the webpage, supported the Clinical Trial Statements. *Id.* at 746-47. As a result, the court rejected the defendant's lack of substantiation argument because the plaintiff alleged provable falsity, such that the citations the defendant referenced did not support the label claims. *Id.* at 750-751. Here, as in *Liou*, the references on Defendants' website actually confirm that the Zicam Products are anything *but* "Clinically Proven to Shorten Colds" and are therefore false.

Further, in *Hughes v. Ester C Co.,* 930 F. Supp. 2d 439, 464-65 (E.D.N.Y. 2013), the plaintiffs alleged that the defendants deceptively marketed Ester-C products with statements on

the product packaging or website that the products may help in preventing or shortening the duration of colds or flu. *Id.* at 465. To support their claims, the plaintiffs referenced scientific studies disputing those claims, which the court found were sufficient to "remov[e] their claims from the lack of substantiation sphere into the affirmative misrepresentation realm." *Id.* at 459. Based on allegations similar to those made by Plaintiff in the Amended Complaint regarding the Zicam Products, the *Hughes* court found that the plaintiffs' allegations "make clear that plaintiffs' asserted claims are not simply based upon a lack of substantiation. Instead, plaintiffs' allegation that defendants have no credible scientific evidence backing up their representations is relevant in this case because Ester-C's website expressly states that there is clinical research supporting its products." *Id.* at *460. "Thus, [i]n light of defendants' alleged representations of scientific backing to its claims of providing superior vitamin C bioavailability, plaintiffs' asserted scientific study — asserting that Ester-C is *not*, in fact, any better than other vitamin-C brands on the market in administering vitamin C to and increasing the body's absorption of the same — is sufficient to state a plausible claim of affirmative misrepresentation." *Id.* at *461.

As in their Motion to Stay, Defendants lean on this Court's rulings in *Aloudi v. Intramedic Rsch. Grp., LLC*, No. 15-cv-00882, 2015 U.S. Dist. LEXIS 89366 (N.D. Cal. July 9, 2015) (Gilliam Jr., J.), and *Racies v. Quincy Bioscience, LLC, No.* 15-cv-00292, 2015 U.S. Dist. LEXIS 65468 (N.D. Cal. May 19, 2015) (Gilliam Jr., J.) to support their argument that the Motion to Dismiss is dispositive. However, Defendants' reliance on those cases falls short.

In *Racies,* the plaintiff alleged that the "clinically tested" allegation at issue was false and that there were no reliable or high-quality, randomized, controlled trials substantiating the representations. 2015 U.S. Dist. LEXIS 89366, at *7-10. The plaintiff further alleged there was no evidence in the public record that any clinical studies were even performed on the product. *Id.* As a result, this Court dismissed the plaintiff's UCL and CLRA claims only as they related to lack of substantiation because the plaintiff failed to allege provable falsehoods. *Id.* However, this Court

allowed the plaintiff to proceed with UCL and CLRA claims based on a theory of false representations. Thus, although the plaintiff could not proceed by pointing to an absence of evidence substantiating the challenged claims, the plaintiff could proceed with claims showing the challenged claims were false. *Id.* Here, Plaintiff seeks to do just that: not making substantiation arguments, and, instead, arguments showing the falsity of claiming a homeopathic product is clinically proven to do anything.

Further, in a later order in *Racies,* this Court denied the defendant's motion for summary judgment based on a lack of substantiation (allowing the case to proceed well past the dismissal phase) after the plaintiff presented an "expert opinion that ma[de] a logical deduction based on several scientific premises" that the subject products did not perform as advertised. In doing so, the Court stated it was "obvious that Plaintiff [wa]s not demanding that Defendant produce evidence to substantiate its claims." *Racies v. Quincy Bioscience, LLC,* No. 15-cv-00292, 2016 U.S. Dist. LEXIS 136193, *13-15 (N.D. Cal Sept. 30, 2016). Referencing *King Bio,* upon which Defendants here rely, this Court stated, "as the court in *King Bio* explained, in a UCL false advertising case, '[t]he falsity of the advertising claims may be established by testing, *scientific literature*, or anecdotal evidence,'" and the plaintiff's presentation of anecdotal evidence from its expert was sufficient to withstand summary judgment for lack of substantiation. *Id.* (quoting *Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 133 Cal. Rptr. 2d 207 (2003)). Thus, even if Plaintiff's California consumer protection claims are dismissed (in part) for lack of substantiation, Plaintiff should be able to proceed with claims showing the Clinically Proven Claim is false, including through the use of expert evidence, like the plaintiff did in *Racies.*

Similarly, *in Aloudi v. Intramedic Rsch. Grp., LLC*, No. 15-cv-00882, 2015 U.S. Dist. LEXIS 89366 (N.D. Cal. July 9, 2015), although the plaintiff challenged the defendant's "clinically proven" claim, the plaintiff sought to prove his allegations by demonstrating the absence or inadequacy of testing, and with general statements from government entities that the

products did not work as represented, which the Court found were "devoid of context, and [] not tied to the Product or Defendant's specific representations about the Product." *Id.* at *13-15.

The instant case is distinct from *Racies* and *Aloudi* because Plaintiff has presented citations and scientific literature illustrating the falsity of Defendants' Clinically Proven Claim, relying on the inability of homeopathic products to be clinically proven to do anything, references buried deep within Defendants' own website, and independent investigation, which is sufficient to withstand dismissal. FAC at ¶¶ 6-12, 29, 37. Accordingly, Defendants' efforts to compare this case to those where the plaintiffs had no points of reference is at odds with the facts.

2. Plaintiff's Breach of Warranty Claims Are Adequately Pled.[10]

Defendants misconstrue Plaintiff's breach of warranty claim, which is founded upon the simple fact that the Zicam Products are not "Clinically Proven," as represented on the product labels and marketing materials. Plaintiff's claims are based on the very straightforward and clear allegation that the Zicam Products are not "Clinically Proven to Shorten Colds" as advertised. "To prevail on a breach of express warranty claim, a plaintiff must prove that the seller "(1) made an affirmation of fact or promise or provided a description of its goods; (2) the promise or description formed part of the basis of the bargain; (3) the express warranty was breached; and (4) the breach caused injury to the plaintiff." *Nathan,* 2019 U.S. Dist. LEXIS 41926, at *21 (citation omitted). Also, "[t]o establish a claim for a breach of implied warranty, the plaintiff must demonstrate that a product is not 'fit for the ordinary purposes for which such goods are used' or fails to 'conform to the promises or affirmations of fact made on the container or label.'" *Id.* at *22.

In *Liou*, discussed *supra*, the plaintiff alleged a breach of express warranty relating to Clinical Trial Statements on a juice product where the defendant sought to rely upon numerous clinical trials published on a government website and supported by a prominent medical university,

[10] Defendants' lack of substantiation arguments do not impact Plaintiff's claims for Breach of Express Warranty (Count IV) or Breach of Implied Warranty of Merchantability (Count V).

but neither of the links the defendant cited to, nor the results on the webpage, supported the Clinical Trial Statements. *Liou*, 491 F. Supp. 3d at 748-749. The defendant sought to dismiss the express warranty claim on the basis that the plaintiff's claims were related to "injuries attributable to defendant's marketing efforts rather than the nature of the product itself." *Id.* at 748. The court rejected this argument, finding that "[s]tatements made by a manufacturer through its advertising efforts can be construed as warranty statements," and the plaintiffs' allegations that defendant's "Clinical Trial Statements to promote the benefits of the product constituted express warranties that became part of the basis of the bargain." *Id.* (citation omitted). Thus, the plaintiff adequately pled the elements of a breach of express warranty. *Id.*

In *Nathan*, discussed *supra*, the plaintiff brought breach of express and implied warranty claims in a case involving weight loss supplements that promised "weight management" and appetite control," which led the plaintiff to believe the product at issue was an effective dietary aid that would aid weight loss when it could not. The defendant sought to dismiss the warranty claims on the basis that plaintiff "fail[ed] to allege breach and/or the requisite element of injury as she does not allege ever taking the product." The court rejected this argument, noting that "[p]laintiff's breach of warranty claim focuses on the Product's labels, not Plaintiff's personal consumption of the product," and thus she plausibly alleged a breach of warranty claim on the theory that the product could not deliver the weight management benefits advertised. *Nathan,* 2019 U.S. Dist. LEXIS 41926, at *21-23. Thus, the products did not conform to the promises or affirmations contained on the label. *Id.*

Here, as in *Nathan* and *Liou*, Plaintiff alleges that the Zicam Products are "not useful for their ordinary purpose of shortening the duration of the common cold" (FAC at ¶ 134), and that the Zicam Products are not "Clinically Proven to Shorten Colds" because they are homeopathic products, which have not undergone the necessary testing to be considered clinically proven, and because Defendants seek to support their Clinically Proven Claim with studies actually proving

that the Products are ineffective. This is more than sufficient to allege a breach of warranty claim.

3. Plaintiff Has Standing to Assert Claims Against Zicam for All Products at Issue.

Defendants attack Plaintiff's standing to bring this case under Rule 12(b)(1) by asserting that she does not have standing to assert claims based on Zicam Products she did not buy. *See* ECF No. 37 at 19. A plaintiff can maintain claims for products that she did not purchase if the other products are substantially similar to the product(s) she did purchase. Numerous courts in the Ninth Circuit have found that "diverse products that bear similar or uniform labels may be considered 'substantially similar.' The critical issue is whether the products are substantially similar with respect to the alleged mislabeling." *Maisel v. S.C. Johnson & Son., Inc.*, No. 21-cv-00413, 2021 U.S. Dist. LEXIS 86203, at *17 (N.D. Cal. May 5, 2021) (quoting *Baum v. J-B Weld Co*., LLC, 2019 U.S. Dist. LEXIS 216052, 2019 WL 6841231, at *5 (N.D. Cal. Dec. 16, 2019)); *see also Sims v. Campbell Soup Co.*, 2018 U.S. Dist. LEXIS 222535, at *9-10 (C.D. Cal. Sep. 24, 2018) (citations omitted and emphasis added) ("…*the 'prevailing view' in the Ninth Circuit" is that class action plaintiffs can bring claims for products they didn't purchase "as long as the products and alleged misrepresentations are substantially similar."* They have also noted that the proper time to answer the substantial similarity question is at the class certification stage, where the court "will have to gauge the typicality of [the plaintiff's] claims and [the plaintiff's] ability to adequately represent the interests of the proposed class.")*; Anderson v. Jamba Juice Co.*, 888 F. Supp. 2d 1000, 1006 (N.D. Cal. 2012) ("If there is a sufficient similarity between the products, any concerns regarding material differences in the products can be addressed at the class certification stage.").

Some courts even state that "[t]here must be substantial similarity between the products at issue ***or*** the alleged misrepresentations must be similar across product lines." *Miller v. Ghirardelli Chocolate Co.*, 912 F. Supp. 2d 861, 869 (N.D. Cal. 2012) (emphasizing that both substantially similar products and substantially similar misrepresentations are not required to satisfy the standard). "[T]he critical inquiry seems to be whether there is sufficient similarity between the

products purchased and not purchased." *Astiana v. Dreyer's Grand Ice Cream, Inc.*, No. C-11-2910 EMC, 2012 WL 2990766, at *11 (N.D. Cal. July 20, 2012). "In applying the 'substantial similarity' test, courts look to a series of factors including whether the challenged products are of the same kind, comprised of largely the same ingredients, and whether each of the challenged products bears the same alleged mislabeling." *Figy v. Frito-Lay N. Am., Inc.*, 67 F. Supp. 3d 1075, 1083 (N.D. Cal. 2014). No one factor is superior, and the products should be assessed overall. *See id.* As indicated, substantially similar misrepresentations satisfy this standard. In *Corbett v. Pharmacare U.S., Inc*, the court considered the plaintiffs' standing to assert claims against products they did not buy. No. 21CV137-GPC(AGS), 2021 WL 2473950, at *10 (S.D. Cal. June 17, 2021). The court held that, "[b]ecause Plaintiffs allege uniformity in the representation on the packaging as well as marketing, [] at this stage of the proceedings, the Court DENIES Defendant's motion to dismiss the claims on the Products Plaintiffs did not purchase." *Id.*

Here, Plaintiff brings this case on behalf of a proposed Class including all California purchasers of the Zicam Products, including: Zicam® Original RapidMelts®, Zicam® ULTRA RapidMelts®, Zicam® Elderberry Citrus RapidMelts®, Zicam® Nasal Swabs, Zicam® Nasal Spray, Zicam® Wild Cherry Lozenges, and/or Zicam® Oral Mist™. *See* Dkt. No. 30 at 20, ¶ 67. Plaintiff herself purchased Zicam Nasal Spray. *See* FAC at ¶¶ 41-42. Contrary to Defendants' contention, Plaintiff expressly alleges that the Zicam Products she did not purchase were substantially similar to the one that she did purchase for numerous reasons, including that they were all of the same Product line and uniformly bear the same misrepresentation on their labels, i.e., the deceptive "Clinically Proven Claim," *See* FAC at ¶¶ 2, 4-5, 9, 11, 13, 19, 28, 35, 63. These allegations clearly address *all* of the Products at issue, and establish that each is substantially similar to the Product that Plaintiff purchased, given that "the Clinically Proven Claim that forms the basis of this action is the same for each Product." FAC at ¶ 30.

Defendants rely on two cases in support of their contention that Plaintiff failed to plausibly

allege facts establishing that all the Zicam Products are substantially similar: *Padilla v. Whitewave Foods Co.*, 2019 WL 4640399, at *9-10 (C.D. Cal. July 26, 2019), and *Dysthe v. Basic Rsch., LLC*, 2011 WL 5868307, at *4 (C.D. Cal. June 13, 2011). However, both cases are inapposite here. In *Padilla*, the court held that, "the FAC lacks sufficient, specific allegations that address the ways in which the Products are alike." 2019 WL 4640399, at *10. Here, Plaintiff has already shown, *supra*, that the Amended Complaint included sufficient, specific allegations regarding the similarities across the Products at issue. Further, *Dysthe* is inapposite because the plaintiff failed to include allegations showing that the products were substantially similar in ingredients, packaging, or marketing. 2011 WL 5868307, at *4. That is not the case here. Finally, Defendants assert that Plaintiff has no standing because the Products at issue do not contain the same ingredients. *See* Mot. at 20. However, this argument has no bearing here because, as noted, "the Clinically Proven Claim that forms the basis of this action is the same for each Product." FAC at ¶ 30. Accordingly, Plaintiff has standing to bring claims for all the Products at issue, as alleged within the Amended Complaint.

4. Plaintiff Has Standing to Sue for Injunctive Relief.

Defendants also attack Plaintiff's standing to sue for injunctive relief. "To have standing to obtain injunctive relief, a plaintiff must allege that a 'real or immediate threat' exists that he will be wronged again." *Rahman v. Mott's LLP*, CV 13–3482 SI, 2014 WL 325241 at *10 (N.D. Cal. Jan. 29, 2014) (citation omitted). "In a class action, '[u]nless the named plaintiffs are themselves entitled to seek injunctive relief, they may not represent a class seeking that relief.'" *Garrison v. Whole Foods Mkt. Grp., Inc.*, 13–CV–05222–VC, 2014 WL 2451290 at *5 (N.D. Cal. June 2, 2014) (quoting *Hodgers–Durgin v. de la Vina*, 199 F.3d 1037, 1045 (9th Cir.1999)).

Courts within the Ninth Circuit have held that a plaintiff has standing to sue for injunctive relief regarding mislabeled or misleading product labeling even when she is aware of the misleading nature of the labeling. *See Lilly v. Jamba Juice Co.*, No. 13-CV-02998-JST, 2015 WL

1248027, at *3 (N.D. Cal. Mar. 18, 2015). To support this holding, the court explained:

> As other courts have already recognized: If the Court were to construe Article III standing for FAL and UCL claims [narrowly], federal courts would be precluded from enjoining false advertising under California consumer protection laws because a plaintiff who had been injured would always be deemed to avoid the cause of the injury thereafter ("once bitten, twice shy") and would never have Article III standing.

Lilly, No. 13-CV-02998-JST, 2015 WL 1248027, at *3 (citing *Henderson v. Gruma Corp.*, 2011 U.S. Dist. LEXIS 41077 at *19–20, 2011 WL 1362188 (C.D. Cal. Apr. 11, 2011)). To deny injunctive relief under these circumstances "would eviscerate the intent of the California Legislature in creating consumer protection statutes because it would effectively bar any consumer who avoids the offending product from seeking injunctive relief[[.]" *Koehler v. Litehouse, Inc.*, 2012 WL 6217635, at *16–17 (N.D. Cal. Dec. 13, 2012).

The *Lilly* court also explained its rationale, emphasizing the implications that injunctive relief has regardless of whether the material misrepresentation is true: "When a consumer discovers that a representation about a product is false, she doesn't know that another, later representation by the same manufacturer is also false. She just doesn't know whether or not it's true. A material representation injures the consumer not only when it is untrue, but also when it is unclear whether or not is true." 2015 WL 1248027, at *3. "[T]he Court [also] conclude[d] that a willingness to consider a future purchase is sufficient [to have standing to represent a 23(b)(2) class]." *Id.*

Here, Plaintiff sufficiently alleged that a real threat exists that she would be wronged again. *See*, *e.g.*, FAC at ¶¶ 41-45. Without injunctive relief, Defendants will continue to use misleading and false marketing for their Products. *See generally* FAC. As the Lilly court put it, "[t]he harms [plaintiff] seek[s] to avoid by bringing this litigation are not just the harms related to purchasing or consuming a mislabeled product, but also the harm of being a consumer in the marketplace who cannot rely on the representations made by Defendants on their product labels." 2015 WL

1248027, at *5. Further, Plaintiff specifically alleged, as required under Rule 23(b)(2), that she "has an intention to purchase the Zicam Products in the future if the Zicam Products are truthfully labeled and not misleading, and are actually clinically proven to shorten colds." FAC at ¶¶ 45, 77 ("Plaintiff has an intention to purchase the Zicam Products in the future if they are truthfully labeled and not misleading, and are actually clinically proven to shorten colds.). The circumstances here are exactly in line with the *Lilly* court's rationale.

In *Maisel,* a case involving allegations of false and misleading advertising regarding plant-based dishwasher tablets, the court allowed the plaintiff to proceed with a claim for injunctive relief where the plaintiff alleged that she "would like to purchase the Products again in the future, despite the fact that the Products were once marred by false advertising or labeling" if the plant based representations were in fact true. *Maisel,* 2021 U.S. Dist. LEXIS 86203, at *17. Citing Ninth Circuit precedent, the court found:

> In the Ninth Circuit, "a previously deceived consumer may have standing to seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the advertising was false at the time of the original purchase, because the consumer may suffer an 'actual and imminent, not conjectural or hypothetical' threat of future harm." [*Davidson v. Kimberly-Clark Corp.*, 889 F.3d 956, 969 (9th Cir. 2018)] (quoting Summers v. Earth Island Inst., 555 U.S. 488, 493, 129 S. Ct. 1142, 173 L. Ed. 2d 1 (2009)). This harm may be demonstrated in two ways: (1) "the consumer's plausible allegations that she will be unable to rely on the product's advertising or labeling in the future, and so will not purchase the product although she would like to," or (2) "the consumer's plausible allegations that she might purchase the product in the future, despite the fact it was once marred by false advertising or labeling, as she may reasonably, but incorrectly, assume the product was improved."

Id. at *19 (collecting cases). Here, as in *Maisel* and the numerous cases cited in the court's order, within the FAC, Plaintiff alleges that she "has an intention to purchase the Zicam Products in the future if they are truthfully labeled and not misleading and are actually clinically proven to shorten colds." FAC at ¶¶ 45, 77. This is sufficient under Ninth Circuit law to state a claim for injunctive relief. Accordingly, Plaintiff has standing to sue for injunctive relief.

CONCLUSION

For all of the reasons set forth above, Plaintiff respectfully requests that this Honorable Court deny Church & Dwight Co., Inc.'s Motion to Dismiss in its entirety.[11]

[11] Should the Court find that Plaintiff does not have standing to seek relief on behalf of consumers who purchased Zicam Products other than the nasal spray, or that Plaintiff's UCL and CLRA claims should be dismissed for lack of substantiation, Plaintiff respectfully requests an opportunity to amend the complaint to add plaintiffs or cure any other potential deficiencies.

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Respectfully submitted,

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